



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/777,149

02/13/2004

Mark Brenton Nottle

Q-79924

4044

23373

7590

02/03/2006

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,149

Applicant(s)

NOTTLE ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/856,689.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/13/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1632

This is a continuation of 09/856,689. The preliminary amendment filed February 13, 2004 has been entered. Claims 15-32 are pending.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-32 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,503,698 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although, the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and 1-15 of '698 contain overlapping subject matter.

Claims 15-32 are drawn to methods for the cryopreservation of embryos and oocytes and methods of producing live animals from embryos using methods that are indistinguishable that of claims 1-15 of '698. Each element of present claims 15-32 can be

Art Unit: 1632

found within the claims of '698 or in the specification definition of each term of the claims.

Thus, at the time of the present invention, it would have been obvious to the ordinary artisan at the time of the present invention to make and use the invention of present claims 15-32 given claims 1-15 of '698.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 recites the limitation "oocytes" in claim 28. There is insufficient antecedent basis for this limitation in the claim. Claim 28 is only drawn to embryos.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15-17 and 20-32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,503,698 B1 (Dobrinsky).

Art Unit: 1632

The applied reference has a common inventor (Nagashima) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Dobrinsky teaches a method for cryopreservation of morulae/blastocyst swine embryos comprising centrifuging zona intact embryos (col. 2, lines 23-26; col. 12, lines 30-32 and col. 13, line 66 to col. 14, line 1), subjecting the centrifuged oocytes to freezing in the presence of a cryoprotectant agent such as glycerol or propylene glycol (col. 13, lines 14-17 and col. 14, lines 9-11), freezing in liquid nitrogen (col. 13, lines 39-42 and col. 15, lines 14-15), freezing the embryos in a straw where the embryos enter by capillary action (col. 13, lines 39-42 and col. 14, lines 9-11), storing the frozen embryos (col. 13, lines 39-42), and a method for producing pigs and piglets comprising thawing the zone intact embryo introducing the embryo into the fallopian tube of a pregnancy competent female pig (col. 12, lines 36-40 and Table 8). Dobrinsky therefore teaches pigs and piglets made from cryopreserved embryos as well as cryopreserved embryos (see cites above). Thus Dobrinsky clearly anticipates the claimed invention.

Claims 15-17 and 20-32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,503,698 B1 (Dobrinsky).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

Art Unit: 1632

was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 and 20-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipate by WO 95/05075 published 24 February 1995 (Nagashima).

Nagashima teaches a method for cryopreservation of swine embryos comprising centrifuging zona intact blastocysts (page 5, line 15; page 11, lines 6-7 and page 17, lines 6-7), subjecting the centrifuged oocytes to freezing in the presence of a cryoprotectant agent such as DMSO, glycerol, ethylene glycol, sucrose or toleharose (page 17, lines 13-17), freezing in liquid nitrogen (page 17, lines 19-21), freezing the embryos in a straw where the embryos enter by capillary action (page 17, lines 19-21), storing the frozen embryos (page 17, lines 19-21), and cryopreserved embryos, and pigs and piglets produced from cryopreserved embryo into females pigs, as well as cryopreserved embryos (page 17, lines 30-32). Thus Nagashima clearly anticipates the claimed invention.

Claims 15, 17, 19 and 28-31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Otoi et al (1997) Cryobiology 34, pp. 36-41.

Otoi teaches the cryopreservation of bovine oocytes comprising centrifuging bovine oocytes, placing the centrifuged oocytes in freezing straws, which load by inherently by capillary action, freezing the centrifuged oocytes in the presence of polypropylene glycol (1,2-propanediol), and storing the frozen embryos in liquid nitrogen for one to three months (page 37, col. 1, parag. 2 to col.2, line 23). Thus, Otoi clearly anticipates the claimed invention.

(f) he did not himself invent the subject matter sought to be patented.

Art Unit: 1632

The present application lists Nottle, Cameron, Beebe and Nagashima as inventors. Dobrinsky lists Dobrinsky and Nagashima as inventors. As the subject matter contained in the present specification is the same as that contained in Dobrinsky, there is serious conflict as to the actual inventors of the claimed subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al (1996) J. Reproduc. Fertil. 106, pp. 135-141 in view of WO 95/05075 published 24 February 1995 (Nagashima).

Nagashima teaches a method for cryopreservation of swine embryos comprising centrifuging zona intact blastocysts (page 5, line 15; page 11, lines 6-7 and page 17, lines 6-7), subjecting the centrifuged oocytes to freezing in the presence of a cryoprotectant agent such as DMSO, glycerol, ethylene glycol, sucrose or toleharose (page 17, lines 13-17), freezing in liquid nitrogen (page 17, lines 19-21), freezing the embryos in a straw where the embryos enter by capillary action (page 17, lines 19-21), storing the frozen embryos (page 17, lines 19-21), and pigs and piglets produced by implanting an embryo into females pigs (page 17, lines 30-32). Nagashima teaches that this method can also be used to cryopreserve embryos of other species than pig (page 10, lines 7-9). However, Nagashima does not teach specifically the cryopreservation of cat embryos. Wolf teaches that in vitro fertilization procedures in cats is critical for the production of cat models of human genetic disease and for the rescue of endangered felids in the wild (page 135, col. 1, lines 9-12). Nagashima offers motivation in stating that the method described permits the

Art Unit: 1632

cryopreservation of pig embryos that subsequently develop into pigs to enhance genetic diversity in piggeries (page 1, lines 8-12 and page 7, lines 3-5). Nagashima also offers motivation in stating that the method of cryopreservation can be used in species other than pig (page 10, lines 7-9). Thus, it would have been obvious to the ordinary artisan to enhance genetic diversity in cat populations by producing cat embryos as described by Wolfe and subject them to the cyropreservation methods of Nagashima so that cat embryos can be produced and then stored, and later transferred to queens for gestation to term. Furthermore, it would have been obvious to use this method for the cryopreservation of any livestock embryo: horse, cow, sheep, goat, llama or alpaca. Therefore, the cited prior provides sufficient teaching, suggestion and motivation to the ordinary artisan at the time of the present invention to provide a reasonable expectation of success in making the claimed invention.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/05075 published 24 February 1995 (Nagashima) in view of Yoshida et al ()1990) J. Reproduc. Fertil. 88, pp. 1-8.

Nagashima teaches a method for cyropreservation of swine embryos comprising centrifuging zona intact blastocysts (page 5, line 15; page 11, lines 6-7 and page 17, lines 6-7), subjecting the centrifuged oocytes to freezing in the presence of a cryoprotectant agent such as DMSO, glycerol, ethylene glycol, sucrose or toleharose (page 17, lines 13-17), freezing in liquid nitrogen (page 17, lines 19-21), freezing the embryos in a straw where the embryos enter by capillary action (page 17, lines 19-21), storing the frozen embryos (page 17, lines 19-21), and pigs and piglets produced by implanting an embryo into females pigs (page 17, lines 30-32). However, Nagashima does not teach specifically the introduction of the thawed embryo into the fallopian tube of a female pig. Yoshida teaches the introduction of pig embryos to the oviducts or Fallopian tubes of female pigs

Art Unit: 1632

(page 2, parag. 3). Nagashima offers motivation in stating that the method described permits the cryopreservation of pig embryos that subsequently develop into pigs to enhance genetic diversity in piggeries (page 1, lines 8-12 and page 7, lines 3-5). Yoshida offers motivation in teaching that the transfer of pig embryos resulted in blastocysts, providing evidence that the oviduct transfer method would permit development of pigs (page 3, parag.4, lines 1-2). Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to enhance genetic diversity in pig populations by producing pig embryos, cryopreserve them, thaw them and transfer the embryos to the oviduct of female pigs and permit gestation to term. The cited prior art provides the requisite teaching, suggestion and motivation at the time of filing such that the ordinary artisan would have had a reasonable expectation of success in reaching the claimed invention.

Claims 15, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otoi et al (1997) Cryobiology 34, pp. 36-41 in view of WO 95/05075 published 24 February 1995 (Nagashima).

Otoi teaches the cryopreservation of bovine oocytes comprising centrifuging bovine oocytes, placing the centrifuged oocytes in freezing straws, which load by inherently by capillary action, freezing the centrifuged oocytes in the presence of polypropylene glycol (1,2-propanediol), and storing the frozen embryos in liquid nitrogen for one to three months (page 37, col. 1, para0g. 2 to col.2, line 23). Nagashima teaches that this method can also be used to cryopreserve embryos of other species than pig (page 10, lines 7-9). Otoi offers motivation in stating that the methods of Nagashima for the freezing of pig embryos can be used in the freezing of bovine oocytes because bovine oocytes as pig embryos contain lipids that negatively affect freezing (page 36, col. 1 to col. 2, bridg. parag.). Thus at the time of the instant invention, it would have been obvious to cryopreserve oocytes as taught by Otoi for any species: horse, pig, sheep, goat, llama or alpaca as taught by Nagashima. The cited

Art Unit: 1632

prior art offers sufficient teaching, suggestion and motivation at the time of filing that the ordinary artisan would have had a reasonable expectation of success at making the claimed invention.

This is a continuation of applicant's earlier Application No. 09/856,689. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

January 30, 2006